

# **Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers**

## **Procedure Manual (Revised 9/10/99)**

**Hospital Infections Program  
Centers for Disease Control and Prevention  
Public Health Service, Department of Health and Human Services  
Atlanta, Georgia**

# **Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers**

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# **Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers**

## **Section 1**

### **Introduction**

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Dear Dialysis Center Personnel:

As you know, bacterial infections are major problems in hemodialysis patients. Therefore the Centers for Disease Control and Prevention (CDC) has established a voluntary surveillance system, "Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers." We would like to invite your dialysis center to participate in this project.

Each month, participating centers will report the number of chronic hemodialysis patients treated, and supply information on patients hospitalized or treated with an intravenous (IV) antimicrobial. Data will be forwarded to the CDC for analysis, and routine reports will be compiled and sent to participating centers. At their option, centers may enter and analyze their own data using programs supplied by CDC. We hope that these data will facilitate quality improvement measures.

This study is entirely voluntary. Dialysis center personnel decide whether to participate, and may elect to discontinue participation at any time. Patient names or personal identifiers will not be reported to CDC.

As stated above, CDC will use the data for surveillance purposes only. However, a condition of participation is your agreement to report outbreaks or other problems of public health importance identified in this surveillance system, and for which you have been contacted by CDC, to the local or state public health authorities.

Thank you for considering participation in this surveillance system.

Yours truly,

Jerome I. Tokars, MD, MPH

Elaine R. Miller, RN

## **Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers**

### **How to Enroll**

1. Familiarize yourself with the protocol and example questionnaires. Discuss participation with your medical director and administrator.
2. Schedule and participate in a teleconference with Elaine Miller (404-639-6422). We will walk you through the process and answer any questions.
3. Complete and sign the Agreement to Participate (Section 2).
4. If your center has an IRB (Internal Review Board), and that IRB wants to review the protocol, then it is your responsibility to submit it to them and obtain approval before starting data collection.
5. Mail the completed Agreement to Participate to  
Elaine Miller  
Centers for Disease Control and Prevention  
1600 Clifton Rd Mailstop E-69  
Atlanta GA 30333
5. After we receive this, we will send you a supply of data collection forms, address labels, and envelopes, and you may begin data collection.

## **Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers**

### **Steps in Data Collection**

1. During the first week of the month, complete the CENSUS FORM
2. During the month, as Hospitalizations and In-unit IV antimicrobial starts occur, record them on the LOG FORM
3. For each row on the LOG FORM, complete one INCIDENT FORM
4. When data collection is complete for a given month, photocopy the forms taking care not to copy the patients' names or social security numbers
5. Mail the photocopies without patient names or social security numbers to Elaine Miller at CDC using the envelopes and address labels supplied

**CENSUS FORM**

Provider number 999999

Month, year            03 / 1999

Record the number of chronic hemodialysis patients who received hemodialysis at your center at least once during the first week of the month.

Count each patient only once. If a patient has both an implanted access (graft or fistula) and a catheter, count this patient as having the catheter.

Vascular access type	Number of chronic hemodialysis patients
Graft	20
Fistula	10
Temporary catheter (noncuffed)	5
Permanent catheter (cuffed)	10
Total patients (= the sum of patients with grafts, fistulas, temporary catheters, and permanent catheters)	45

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

## LOG.

Form Approved OMB No. 0920-0442 Exp. date:

2/1/2002

Complete one row for each hospitalization or in-unit IV antimicrobial start. Complete an Incident Form for each row on this Log.

REMOVE THIS COLUMN BEFORE MAILING TO CDC	Provider number 999999 Year 1999				
Patient's name	Date mm / dd	Circle H or A H=hospitalization A=IV antimicrobial start	Problem	LOG Number	Incident Form Complete d
John Smith	03/02	<input checked="" type="radio"/> H <input type="radio"/> A	Chest pain	1	<input checked="" type="radio"/> Y
Jane Doe	03/02	<input type="radio"/> H <input checked="" type="radio"/> A	Fever = 102° F	2	<input checked="" type="radio"/> Y
Bill Miller	03/08	<input checked="" type="radio"/> H <input type="radio"/> A	Diabetic foot ulcer	3	<input checked="" type="radio"/> Y
Marie Rush	03/20	<input checked="" type="radio"/> H <input checked="" type="radio"/> A	Infected catheter	4	<input checked="" type="radio"/> Y
	/	<input type="radio"/> H <input type="radio"/> A		5	Y
	/	<input type="radio"/> H <input type="radio"/> A		6	Y
	/	<input type="radio"/> H <input type="radio"/> A		7	Y
	/	<input type="radio"/> H <input type="radio"/> A		8	Y
	/	<input type="radio"/> H <input type="radio"/> A		9	Y
	/	<input type="radio"/> H <input type="radio"/> A		10	Y
	/	<input type="radio"/> H <input type="radio"/> A		11	Y
	/	<input type="radio"/> H <input type="radio"/> A		12	Y
	/	<input type="radio"/> H <input type="radio"/> A		13	Y
	/	<input type="radio"/> H <input type="radio"/> A		14	Y
	/	<input type="radio"/> H <input type="radio"/> A		15	Y
	/	<input type="radio"/> H <input type="radio"/> A		16	Y
	/	<input type="radio"/> H <input type="radio"/> A		17	Y
	/	<input type="radio"/> H <input type="radio"/> A		18	Y
	/	<input type="radio"/> H <input type="radio"/> A		19	Y
	/	<input type="radio"/> H <input type="radio"/> A		20	Y

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Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.



**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First <b>John</b> MI <b>B.</b> Last <b>Smith</b>		2. Social security number: <b>123-45-6789</b>	
<b>REMOVE TOP BEFORE MAILING</b>			
3. Provider number 999999		4. Date <b>03 / 02 /1999</b>	
5. LOG Number <b>1</b>			
6. Incident type (circle H and/or A):			
<input checked="" type="radio"/> H Hospitalization  6a. If this is a hospitalization, answer: After return to unit, was IV vancomycin given? <input checked="" type="radio"/> N Y		A = In-unit IV antimicrobial start  6b. If this is an in-unit IV antimicrobial start, answer: Was IV vancomycin started? N Y	
7. Vascular accesses (circle all that the patient has): <input checked="" type="radio"/> 1 = graft    2 = fistula    3 = temporary catheter    4 = permanent catheter			
8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):			
a. Vascular access <b>infection</b> (pus, or redness, or increased swelling at vascular access site) b. Vascular access problem <b>WITHOUT</b> infection (clotting, bleeding, etc) c. Fever (\$100F oral or \$101F rectal) d. Wound ( <b>NOT</b> related to vascular access) with pus or increased redness e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray) f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated) <input checked="" type="radio"/> g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc) h. Other, specify:			
9. Vascular access removed? <input checked="" type="radio"/> N Y			
9a. If yes, circle the access that was removed: 1 = graft    2 = fistula    3 = temporary catheter    4 = permanent catheter			
10. Were <b>blood</b> cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission? <input checked="" type="radio"/> N Y U			
10a. If yes, result 1 = positive    2 = negative    3 = unknown			
10b. If <b>positive</b> , suspected source of positive blood culture:			
1 = vascular access    2 = a source other than the vascular access    3 = contamination    4 = uncertain			
10c. If <b>blood</b> cultures were positive, complete the following:			
List organisms isolated from blood		Antimicrobial susceptibility	
List one code* or name per row	Methicillin, Oxacillin, or Nafcillin	Vancomycin	
_____	S   I   R   U	S   I   R   U	
_____	S   I   R   U	S   I   R   U	
11. Comments			
Fever: 100 F = 37.8 C    101 F = 38.3 C    N=no    Y=yes    U=unknown    S=susceptible    I=intermediate R=resistant *SA= <i>S. aureus</i> SE= <i>S. epidermidis</i> CNS=coagulase-negative staphylococci    PA= <i>P. aeruginosa</i>			

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Public reporting burden of this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First <b>Jane</b> MI <b>E.</b> Last <b>Doe</b>		2. Social security number: <b>987-65-4321</b>	
<b>REMOVE TOP BEFORE MAILING</b>			
3. Provider number 999999		4. Date <b>03 /02 / 1999</b>	
5. LOG Number <b>2</b>			
6. Incident type (circle H and/or A):			
H = Hospitalization		<input checked="" type="radio"/> A = In-unit IV antimicrobial start	
6a. If this is a hospitalization, answer: After return to unit, was IV vancomycin given? N Y		6b. If this is an in-unit IV antimicrobial start, answer: Was IV vancomycin started? N <input checked="" type="radio"/> Y	
7. Vascular accesses (circle all that the patient has): 1 = graft 2 = fistula 3 = temporary catheter <input checked="" type="radio"/> 4 = permanent catheter			
8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):			
<input checked="" type="radio"/> a. Vascular access <b>infection</b> (pus, or redness, or increased swelling at vascular access site) b. Vascular access problem <b>WITHOUT</b> infection (clotting, bleeding, etc) <input checked="" type="radio"/> c. Fever (\$100F oral or \$101F rectal) d. Wound ( <b>NOT</b> related to vascular access) with pus or increased redness e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray) f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated) g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc) h. Other, specify:			
9. Vascular access removed? <input checked="" type="radio"/> N Y			
9a. If yes, circle the access that was removed: 1 = graft 2 = fistula 3 = temporary catheter 4 = permanent catheter			
10. Were <b>blood</b> cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission? N <input checked="" type="radio"/> Y U			
10a. If yes, result 1 = positive <input checked="" type="radio"/> 2 = negative 3 = unknown			
10b. If <b>positive</b> , suspected source of positive blood culture:			
1 = vascular access 2 = a source other than the vascular access 3 = contamination 4 = uncertain			
10c. If <b>blood</b> cultures were positive, complete the following:			
List organisms isolated from blood	Antimicrobial susceptibility		
List one code* or name per row	Methicillin, Oxacillin, or Nafcillin	Vancoymcin	
	S I R U	S I R U	
	S I R U	S I R U	
11. Comments			
Fever: 100 F = 37.8 C 101 F = 38.3 C N=no Y=yes U=unknown S=susceptible I=intermediate R=resistant *SA= <i>S. aureus</i> SE= <i>S. epidermidis</i> CNS=coagulase-negative staphylococci PA= <i>P. aeruginosa</i>			

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2/1/2002

**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First <b>Bill</b> MI <b>W.</b> Last <b>Miller</b>		2. Social security number: <b>001-01-0001</b>	
<b>REMOVE TOP BEFORE MAILING</b>			
3. Provider number <b>999999</b>		4. Date <b>03 /08 /1999</b> 5. LOG Number <b>3</b>	
6. Incident type (circle H and/or A):			
<input checked="" type="radio"/> H = Hospitalization		A = In-unit IV antimicrobial start	
6a. If this is a hospitalization, answer: After return to unit, was IV vancomycin given? <input checked="" type="radio"/> N Y		6b. If this is an in-unit IV antimicrobial start, answer: Was IV vancomycin started? N Y	
7. Vascular accesses (circle all that the patient has): <input checked="" type="radio"/> 1 = graft 2 = fistula 3 = temporary catheter 4 = permanent catheter			
8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):			
a. Vascular access <b>infection</b> (pus, or redness, or increased swelling at vascular access site)			
b. Vascular access problem <b>WITHOUT</b> infection (clotting, bleeding, etc)			
c. Fever (\$100F oral or \$101F rectal)			
<input checked="" type="radio"/> d Wound ( <b>NOT</b> related to vascular access) with pus or increased redness			
e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray)			
f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated)			
g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc)			
h. Other, specify:			
9. Vascular access removed? <input checked="" type="radio"/> N Y			
9a. If yes, circle the access that was removed: 1 = graft 2 = fistula 3 = temporary catheter 4 = permanent catheter			
10. Were <b>blood</b> cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission? N <input checked="" type="radio"/> Y U			
10a. If yes, result <input checked="" type="radio"/> 1 = positive 2 = negative 3 = unknown			
10b. If <b>positive</b> , suspected source of positive blood culture:			
1 = vascular access <input checked="" type="radio"/> 2 a source other than the vascular access 3 = contamination 4 = uncertain			
10c. If <b>blood</b> cultures were positive, complete the following:			
List organisms isolated from blood List one code* or name per row		Antimicrobial susceptibility	
		Methicillin, Oxacillin, or Nafcillin	Vancomycin
SA		<input checked="" type="radio"/> S I R U	<input checked="" type="radio"/> S I R U
		S I R U	S I R U
11. Comments			
Fever: 100 F = 37.8 C 101 F = 38.3 C N=no Y=yes U=unknown S=susceptible I=intermediate R=resistant *SA= <i>S. aureus</i> SE= <i>S. epidermidis</i> CNS=coagulase-negative staphylococci PA= <i>P. aeruginosa</i>			

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**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First <b>Marie</b> MI <b>H.</b> Last <b>Rush</b>		2. Social security number: <b>444-44-4444</b>	
<b>REMOVE TOP BEFORE MAILING</b>			
3. Provider number 999999		4. Date <b>03 / 20 /1999</b> 5. LOG Number <b>4</b>	
6. Incident type (circle H and/or A):			
<input checked="" type="radio"/> Hospitalization  6a. If this is a hospitalization, answer: After return to unit, was IV vancomycin given? <input checked="" type="radio"/> N Y		<input checked="" type="radio"/> In-unit IV antimicrobial start  6b. If this is an in-unit IV antimicrobial start, answer: Was IV vancomycin started? N <input checked="" type="radio"/> Y	
7. Vascular accesses (circle all that the patient has): 1 = graft <input checked="" type="radio"/> 2 = fistula <input checked="" type="radio"/> 3 = temporary catheter 4 = permanent catheter			
8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):			
<input checked="" type="radio"/> a. Vascular access <b>infection</b> (pus, or redness, or increased swelling at vascular access site) b. Vascular access problem <b>WITHOUT</b> infection (clotting, bleeding, etc) c. Fever (\$100F oral or \$101F rectal) d. Wound ( <b>NOT</b> related to vascular access) with pus or increased redness e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray) f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated) g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc) h. Other, specify:			
9. Vascular access removed? N <input checked="" type="radio"/> Y			
9a. If yes, circle the access that was removed: 1 = graft 2 = fistula <input checked="" type="radio"/> 3 = temporary catheter 4 = permanent catheter			
10. Were <b>blood</b> cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission? N <input checked="" type="radio"/> Y U			
10a. If yes, result <input checked="" type="radio"/> 1 = positive 2 = negative 3 = unknown			
10b. If <b>positive</b> , suspected source of positive blood culture:			
<input checked="" type="radio"/> 1 = vascular access 2 = a source other than the vascular access 3 = contamination 4 = uncertain			
10c. If <b>blood</b> cultures were positive, complete the following:			
List organisms isolated from blood	Antimicrobial susceptibility		
List one code* or name per row	Methicillin, Oxacillin, or Nafcillin	Vancoymcin	
<b>E. faecium</b>	<input checked="" type="radio"/> S I R U	<input checked="" type="radio"/> S I R U	
	S I R U	S I R U	
11. Comments <b>temporary catheter infected</b>			
Fever: 100 F = 37.8 C 101 F = 38.3 C N=no Y=yes U=unknown S=susceptible I=intermediate R=resistant *SA= <i>S. aureus</i> SE= <i>S. epidermidis</i> CNS=coagulase-negative staphylococci PA= <i>P. aeruginosa</i>			

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# **Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers**

## **Section 2**

### **Agreement to Participate**

Agreement to participate  
Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers

Form Approved OMB No. 0920-0442 Exp. date: 2/1/2002

Name of dialysis center: \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

Phone \_\_\_\_\_

Fax \_\_\_\_\_

Email address \_\_\_\_\_

HCFA provider number \_\_\_\_\_

As described in the introductory invitation letter, CDC will use the data for surveillance purposes only, and has obtained an assurance of confidentiality to protect the data. However, a condition of participation is your agreement to report outbreaks or other problems of public health importance identified in this surveillance system, and for which you have been contacted by CDC, to the local or state public health authorities.

We agree to participate in "Surveillance for Bloodstream Infection and Vascular Access Infections in Outpatient Hemodialysis Centers." We understand that participation is voluntary and we can discontinue our participation at any time.

The primary contact person listed below agrees that data collected and transmitted to Centers for Disease Control and Prevention (CDC) will be complete and accurate, to the best of his or her knowledge.

Primary contact person:

Name (printed) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Medical Director or Administrator

Name (printed) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

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Agreement to Participate, page 2

Name of dialysis center: \_\_\_\_\_

HCFA Provider number \_\_\_\_\_

Answer the following questions based on your dialysis center's policy. If your center has no policy, answer based on the most commonly followed procedure.

For puncture of a graft or fistula, answer:

- N Y This dialysis center has a written policy for puncture of graft/fistula
- N Y Area washed with antibacterial soap
- N Y Area washed with other, specify: \_\_\_\_\_
- N Y Puncture site wiped with povidone-iodine (betadine, iodophor)
- If yes,
- Number of pads/swabs used: \_\_\_\_\_
- Is the povidone-iodine left on 3 minutes or allowed to dry? N Y
- N Y Puncture site wiped with other, specify: \_\_\_\_\_

For dressing change of central catheters, answer:

- Y N This dialysis center has a written policy for catheter dressing changes.
- Y N Staff person is required to wear a mask during dressing change.
- Y N Patient is required to wear a mask during dressing change.
- Y N Staff are required to wear clean nonsterile gloves to remove old dressing
- Y N Staff are required to wear sterile gloves to clean the area and apply new dressing.
- Y N If drainage is found at the exit site (i.e., the place where the catheter enters the skin), drainage is removed with (specify): \_\_\_\_\_
- Y N Exit site wiped with povidone-iodine (betadine, iodophor).
- Y N Antibacterial ointment applied to exit site during dressing change.
- Y N Dressing applied over exit site at least once weekly.

Specify type of dressing used over catheter:

\_none \_gauze \_band-aid \_transparent \_other (specify) \_\_\_\_\_

For access of central catheters, answer:

- Y N This dialysis center has a written policy for access of catheter.
- Y N Staff person is required to wear a mask during access.
- Y N Patient is required to wear a mask during access
- Y N Staff are required to wear sterile gloves to clean the area and do access.
- Y N Catheter port site (usually a rubber diaphragm)
- wiped with povidone-iodine (betadine, iodophor).

If yes,

Number of pads/swabs used: \_\_\_\_\_

Is the povidone-iodine left on 3 minutes or allowed to dry? Y N

- Y N Catheter port site wiped with other (specify) \_\_\_\_\_

Specify type of dressing used over catheter:

\_none \_gauze \_band-aid \_transparent \_other (specify) \_\_\_\_\_

Regarding antimicrobial use, answer

- Y N This center has a written policy regarding antimicrobial use
- Y N This center has access to a computerized listing of antimicrobials received by patients

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

## Institutional Review Board Forms

The “IRB Form 1” or “IRB Form 2” (etc.) explained in the earlier version of the procedure manual are no longer required. It is **NOT** necessary to have a Single Project Assurance (SPA) or Multiple Project Assurance (MPA) to participate in this project. Centers are not considered to be “performance centers.” This decision was made based on the following points.

1. The data are collected routinely by the dialysis centers.

This is an observational epidemiological study without any intervention. Existing data are recorded, and patient care is not altered. These data are collected routinely by dialysis centers.

2. Only dialysis center personnel who have access to the data as part of practice will complete forms and send data to CDC.

Data collection is performed by dialysis center personnel who would routinely have access to this information as part of their regular jobs.

3. CDC has obtained an “Assurance of Confidentiality” for this project.

4. CDC will never report any information on individuals back to dialysis centers.

It is planned to produce reports with summary statistics only. No data on individuals will be reported back to dialysis centers. Personnel at the dialysis centers will have this data on individuals anyway, and there would be no need or reason for CDC to report it back to them.

The CDC IRB has approved the study and this is all this is required by us. If your center has an IRB, and that IRB wants to review the protocol, then it is your responsibility to submit it to them and obtain approval before starting data collection



## Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers

Surv27.wpd      08/11/1999

### **PURPOSES**

1. To provide a method for individual hemodialysis centers to record and track rates of bloodstream and vascular access infections, hospitalizations, and intravenous (IV) antimicrobial starts.
2. To provide a method for Centers for Disease Control and Prevention (CDC) to aggregate, compare, and distribute these data to cooperating dialysis centers and the public health and medical communities.
3. To use these data to prevent infections and slow the spread of antimicrobial resistance.

### **SUMMARY**

Bloodstream and vascular access infections are a threat to hemodialysis patients. However, there are few studies of rates of such infections, and there are no standardized methods for ongoing data collection. Because of frequent hospitalizations and receipt of antimicrobials, hemodialysis patients are at high risk for infection with drug-resistant bacteria. This protocol outlines creation of a voluntary national surveillance system. Each month, dialysis center personnel will record the number of chronic hemodialysis patients that they treat (broken down into four types of vascular access). A one-page form will be completed for each hospitalization or in-unit intravenous (IV) antimicrobial start among these patients. These data will allow

calculation, stratified by type of vascular access, of rates of access-related bloodstream infection, vascular access infections, hospitalizations, in-unit IV antimicrobial starts, and uses of vancomycin. For individual dialysis centers, this surveillance system will provide a simple and standardized method to record data, calculate rates, and compare rates over time. It is hoped that collection and examination of these data will lead to quality improvement measures. For government and the medical and public health communities, aggregation of these data from many dialysis centers will provide a wealth of information which is not currently available.

## **INTRODUCTION**

At the end of 1996, 183,022 patients were being treated with chronic hemodialysis at 3,015 dialysis centers in the United States. Hemodialysis patients require a vascular access, a large blood vessel or catheter that can be punctured to remove blood. The blood is passed through a dialyzer to remove wastes and finally returned to the patient through the vascular access. Bacteremias and localized infections of the vascular access site are thought to be common in hemodialysis patients (1).

The only large recent studies of infections in hemodialysis patients have been conducted in France (1) and Canada (2). Although sophisticated surveillance systems for nosocomial infections in hospitalized patients in the United States exist (3), there are no standardized methods for surveillance for infections in outpatient hemodialysis centers. An important strategy for preventing infections, or any other complication, is to count them in a systematic manner, calculate appropriate rates of occurrence, and compare the rates over time. This proposed surveillance system is intended to assist dialysis centers in using this approach.

Reported local signs of vascular access infection include erythema, warmth, induration, swelling, tenderness, breakdown of skin, loculated fluid, or purulent exudate (4-6). Among vascular access types, arteriovenous fistulas created from the patient's own blood vessels have the lowest rates of infection; grafts constructed from synthetic materials have intermediate risk; and central catheters have the highest risk (2,7,8). Because type of vascular access is the strongest known predictor of infection, this surveillance system will collect data on the population of hemodialysis patients at risk stratified by type of vascular access. This will allow calculation of rates separately for the different types of vascular access.

The rapid increase in vancomycin-resistant enterococci (VRE) in the United States is linked to use of antimicrobials, including vancomycin (9,10). Vancomycin is thought to be used commonly in dialysis patients because it can be administered once a week and is effective against two common pathogens, coagulase-negative staphylococci and *Staphylococcus aureus*. Strains of *S. aureus* with intermediate susceptibility to vancomycin have been isolated from only four patients worldwide. Of these four, one was receiving temporary dialysis and two were receiving chronic dialysis; all had received prolonged courses of vancomycin (11)(Centers for Disease Control and Prevention [CDC], unpublished data). Therefore, a secondary purpose of this surveillance system is to record rates of and syndromes prompting use of intravenous (IV) antimicrobials in hemodialysis centers.

Participation in this project is voluntary and centers may discontinue participation at any time. Only chronic hemodialysis patients will be studied. For these patients, an "Incident Form" is completed for each hospitalization or in-unit IV antimicrobial start. It is assumed that if a patient has a significant bacterial infection, he/she will be either hospitalized or started on an IV antimicrobial in the dialysis unit.

Therefore, the Incident Forms will have data on all patients likely to have an infection.

Among infections, this project focuses on bacteremias and vascular access infections.

Information on other infections is collected in a simplified manner to help define the indications for antimicrobial use and determine whether bacteremia is access-related, caused by an infection elsewhere, or of no identifiable origin. The distinction is important, because measures to prevent access-related bacteremia are different from those to prevent other bacteremias.

Dialysis center personnel may collect data on paper forms and send the forms to CDC, where the data will be entered into a computer and reports generated. However, if desired, individual center personnel may find it beneficial to enter their own data into a computer, perform analysis, and generate reports on-site that can be used for quality control efforts. For such centers, CDC will develop and supply simple computer programs to facilitate data entry and analysis. All data, regardless of whether collected on paper forms or in computer databases, will be sent to CDC, where it can be aggregated and summary reports prepared. These data will provide a wealth of information currently lacking about infectious complications suffered by chronic hemodialysis patients.

## **STUDY DESIGN**

### **Participation**

CDC will solicit dialysis centers to participate in this project through a letter to dialysis centers (Attachment 1a). Centers treating primarily children may participate; data from these pediatric units will be analyzed and presented separately from the majority of units that treat primarily adults. Participation in this project is voluntary on the part of dialysis centers. The medical director, physicians,

administrator, head nurse, and other key personnel should be familiar with the project and agree to participate. Centers may collect data for as little as one month or for an indefinite period, as desired. Collection of data for a longer period will result in information that is of more benefit to the dialysis center.

Centers wishing to participate should complete and submit Attachment 1, Agreement to Participate. This form requests information on infection control precautions and on policies for antimicrobial use. Centers may discontinue participation at any time. For centers that continue to participate, the Agreement to Participate will be filled out once per year to update information.

The three forms for ongoing data collection include information on:

For hospitalizations:

1. that patients have been hospitalized.
2. the problem or diagnoses prompting hospital admission, especially whether the patient had signs and symptoms of access infection.
3. the results of blood cultures done in the hospital soon after admission.

For in-unit IV antimicrobial starts:

4. that patients were started on an IV antimicrobial in-unit.
5. the problem or diagnosis prompting use of the IV antimicrobial, especially whether patients had signs and symptoms of access infection.
6. the results of blood cultures done in the unit.

These steps will be easily accomplished at some centers through use of computerized databases or billing records, but will be a major challenge at other centers. Before participating, centers should, at

a minimum, be sure that they can perform 1 and 4-6 from the list above. Data will be most useful to dialysis centers if they can perform all six.

Only chronic hemodialysis patients will be studied.

## **Data collection**

Ongoing data collection will use three forms (Attachments 2, 3, and 4). Center personnel may record data on paper forms and forward the forms to CDC after removing patients' names. Center personnel alternately could enter the data into a computer database supplied by CDC. Such data will be sent to CDC on diskette or by the Internet with all patient identifiers removed or encrypted.

**CENSUS FORM.** The Census Form (Attachment 2) is used to record the number of chronic hemodialysis patients with each access type who received hemodialysis at your center at least once during the first week of the month.

Count each patient only once; if the patient has both a implanted access (fistula or graft) and a catheter, count the patient as having a catheter.

- Provider number: the center's provider number as assigned by HCFA.
- Current month and year, in mm/yyyy format (e.g., 07/1998)
- Grafts: the number of patients having AV grafts
- Fistulas: the number of patients having AV fistulas
- Temporary catheters: the number of patients having temporary (noncuffed) catheters
- Permanent catheters: the number of patients having permanent (cuffed) catheters
- Total patients: the total number of chronic hemodialysis patients as of the first of the month, equals the sum of patients who receive dialysis via grafts + fistulas + permanent catheters +

temporary catheters.

LOG. One row of the Log (Attachment 3) is completed for each Incident (hospital admission or in-unit IV antimicrobial start). Include only chronic hemodialysis patients. There is room for 20 incidents on each form. Start a new log form each month. Information written on the Log will not be used in data analysis. This is used only to help insure that an Incident Form (see below) is completed whenever necessary.

- Provider number. The center's provider number as assigned by HCFA.
- Year. Use 4 digits, e.g., 1998.
- Patient name. Remove this column before sending the form to CDC.
- Date. The month and day of the hospitalization or IV antimicrobial start.
- Circle H or A. Circle H if this is a hospitalization, A if it is an in-unit IV antimicrobial start, or both if the IV antimicrobials were started in the unit and the patient was subsequently admitted to the hospital.
- Problem. Write in a brief description of the primary problem.
- Incident form completed. An Incident Form should be completed for each row on the Log.

When the Incident Form is complete, circle Y on the Log Form.

INCIDENT FORM. One Incident Form (Attachment 4) is completed for each hospital admission or in-unit IV antimicrobial start. Include only chronic hemodialysis patients. Information recorded on this form will be used for analysis purposes.

1. Name: First    MI    Last. Refers to the patient's name. Remove this section of the form before sending it to CDC.

2. Social security number. Remove this section of the form before sending it to CDC.
3. Provider number. The center's provider number as assigned by HCFA.
4. Date: the month, day, and year (mm/dd/yyyy, i.e., 07/23/1998) of the hospitalization or IV antimicrobial start.
5. Number: Number the incident forms consecutively starting with 1. Each new month will start with 1.
6. Incident type. Circle "H" if this is a hospitalization, "A" if it is an in-unit IV antimicrobial start, or both if the IV antimicrobials were started in the unit and the patient was subsequently admitted to the hospital.
  - 6a. If a hospital admission, answer: After return to the unit, IV vancomycin given?  
  
This refers to IV vancomycin given in the dialysis unit after the patient has been discharged from the hospital and returns to the dialysis unit.
  - 6b. If an in-unit IV antimicrobial start, answer: IV vancomycin started? This question is completed only if IV antimicrobials were started in the dialysis unit. If the antimicrobial regimen included vancomycin, circle Y. Otherwise, circle N.
7. Vascular accesses (circle all that the patient has): Circle one or more numbers to indicate the patient's current vascular access: fistula, graft, temporary (noncuffed) catheter, or permanent (cuffed) catheter.
8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one).

If the patient was hospitalized, this question refers to problems causing the admission. If this is



an in-unit IV antimicrobial start, this question refers to problems causing the antimicrobial to be started.

a. Vascular access infection (pus, or redness, or increased swelling at vascular access site). Do not circle “a” if the patient merely has fever of unknown source (circle “c” instead). If the patient is felt to have an access infection, but does not have pus, redness, or increased swelling, do not circle “a” (circle “h” instead). If the patient has more than one access, indicate under “11. Comments” (at the bottom of the form) which access had the pus, redness, or increased swelling.

b. Vascular access problem WITHOUT infection (bleeding, clotting, etc).

c. Fever (≥100°F oral or ≥101°F rectal). Circle this category if the patient has a fever with or without other symptoms or signs of infection.

d. Wound (NOT related to vascular access) with pus or increased redness.

This could be the site of a former surgical procedure NOT related to the access, a decubitus ulcer, a diabetic foot ulcer, etc. Do not circle “d” if the patient has a wound problem, but does not have pus or increased redness (circle “h” instead).

e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray). Do not circle this choice if the patient is considered to have bronchitis or pneumonia, but does not have an infiltrate seen on chest X-ray (circle “h” instead).

f. Urinary tract infection (UTI) (urine culture with >100,000 organisms/ml with not more than two species isolated). If more than two species are isolated, it is likely the specimen was contaminated during collection, and the organisms are actually not causing

an infection. Do not circle this choice if the patient is felt to have a UTI, but does not meet the criteria for this category (circle “h” instead).

g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc).

Include arrhythmias, congestive heart failure, noninfective pericarditis, suspected or confirmed myocardial infarction (heart attack), cerebrovascular accident, stroke, etc.

h. Other, specify: If the primary reason for hospitalization or IV antimicrobial start is not listed under a-g above, print it neatly and concisely here. Use the physician’s assessment, if available; otherwise use the nurse’s assessment. Examples are abdominal pain (specify etiology if known), bronchitis, cholecystitis, confusion, diverticulitis, electrolyte imbalance (calcium, potassium, etc), fluid overload, peritoneal dialysis catheter infection, prostatitis, sinusitis, surgery, or tooth extraction. If the diagnosis is unknown, write in “Unknown.”

9. Vascular access removed. Circle N or Y to indicate whether the vascular access was removed as part of this incident.

9a. If yes, circle the access that was removed:

Circle the appropriate number of the access removed. If more than one access was removed, circle more than one number.

10. Were any blood cultures drawn in the unit, or within 1 day of hospital admission? Circle N, Y, or U. If the patient was hospitalized, we are looking for blood cultures taken within 1 day before to 1 day after hospital admission—do not record the many blood cultures a patient may have during a hospital admission. If the patient was hospitalized and you don’t know if blood

cultures were done, circle U.

10a. If yes, result 1=positive 2=negative 3=unknown. You would circle U only if the patient had been hospitalized and blood culture results are not available.

10b. If positive, suspected source of positive blood culture:

1=vascular access 2=a source other than the vascular access

3=contamination 4=uncertain.

More than one of the above may be circled.

Circle "1=vascular access" only if there is some objective evidence of vascular access infection (i.e., drainage, pus, redness, swelling, pain, an open area, or a positive culture from the access showing the same organism found in the blood)—do not circle this category if the patient has a positive blood culture of no known etiology (instead, circle 4=uncertain).

Circle 2 if the patient has an infection at another site that could have caused the positive blood culture. Circle this option if either (a) or (b) is true: (a) a culture from another site (e.g, leg wound, urine) shows the same organism found in the blood; (b) there is clinical evidence of infection at another site, but a culture was not taken from it.

Circle 3 if the organism is thought to be a contaminant. Circle this option if either the laboratory or the attending physician states that the positive blood culture is suspected to be a contaminant. Blood cultures positive for the following organisms may represent contamination: coagulase-negative staphylococcus (e.g., *S. epidermidis*, CNS), diphtheroids, *Propionibacterium* species, or *Bacillus* species. Coagulase-negative staphylococci (CNS) include *S. epidermidis* and

several other species of *Staphylococcus* but NOT *S. aureus*. Diphtheroids may be reported by the laboratory simply as “diphtheroids” or as a name starting with “*Corynebacterium*” such as “*C. ulcerans*.” Contamination is more likely if only one blood culture “set” is positive for the organism. Each blood culture “set” usually consists of 20 ml of blood inoculated into two blood culture bottles (10 ml into each bottle); more than 2 bottles filled from a single venipuncture should be interpreted as only one set.

Circle 4 = uncertain if there is insufficient evidence to decide among the three previous categories.

10c. If blood cultures were positive, complete the following:

List organisms isolated from blood. List one code or organism per row.

If the blood cultures were positive, indicate which organism or organisms grew. On paper forms: Write in SA for *S. aureus*, SE for *S. epidermidis*, CNS for coagulase-negative staphylococci or PA or *Pseudomonas aeruginosa*. Otherwise, neatly print the first letter of the genus and the entire species name (e.g., *K. pneumoniae*, *B. cepacia*, *C. diversus*, *S. marcescens*). If you do not know the organism, write in “Unknown.”

On the computer data entry screen: highlight the appropriate organism name or category in the drop-down list.

There is room for two organisms found in blood cultures; if more than two organisms were isolated from blood, list these under “Comment” (see below).

- Methicillin, oxacillin, or nafcillin. Answer R if the organism was reported to be resistant to oxacillin, methicillin, or nafcillin. If it is susceptible to one of these, circle S.

If reported to be intermediate, circle I. If the organism was not tested, or if you do not have the result, circle U (unknown). Note that if a *S. aureus* isolate is resistant to oxacillin, it is also resistant to methicillin and is called a methicillin-resistant *S. aureus* (MRSA).

- Vancomycin. Circle S if the organism was susceptible to vancomycin, I if intermediate, or R if resistant. If the organism was not tested, or if you do not have the result, circle U (unknown). Note that if an enterococcus (e.g., *E. faecium* or *E. faecalis*) is resistant to vancomycin, it is a vancomycin-resistant enterococcus (VRE).

11. Comment(s). Use this to record any comment, additional explanation, other infection, or information that is not recorded elsewhere.

The answers to some questions about hospitalizations may not be known, especially initially. In such instances, only available information should be completed. When the patient is discharged from the hospital and returns to the dialysis center, update any information available. Circle or write in “Unknown” as appropriate if information is still not available; center personnel are not expected to go to extraordinary lengths to obtain information from hospitalizations.

To obtain data from hospital admissions, center personnel could request that physicians record the following in the patient’s dialysis unit chart as soon as possible after the hospital admission: the reason for hospital admission, whether signs of access infection (pus, redness or increased swelling) were present at the time of admission, and whether the patient had a positive blood culture within 1 day after hospital admission. Recording these data in the dialysis unit chart would be consistent with good record-

keeping and will facilitate general quality control measures. Other data needed to complete the Incident Form could be ascertained after the patient is discharged from the hospital and returns to the unit.

Each time a patient is hospitalized (no matter how soon after the last hospitalization), a new entry should be made on the Log and a new Incident Form filled out. If the patient was hospitalized and returns to the dialysis unit on IV antimicrobials, do NOT make a new entry on the Log and do NOT complete a second Incident Form.

If IV antimicrobials are stopped for less than 21 days and then restarted, this is NOT considered a new incident (therefore do not make an entry on the Log and do NOT complete a new Incident Form). However, if IV antimicrobials are stopped for 21 days or more and then restarted, this is considered a new incident. Make an entry on the Log and complete a new Incident Form.

### **Data validation**

Dialysis center personnel should strive for day-to-day accuracy in data collection. Although not a formal part of the surveillance system, several methods to spot-check or validate the data are possible. If a computerized laboratory database is available, dialysis center personnel could print out a list of all blood culture results for a given month and compare the list with the Log and Incident Forms to insure that all positive blood cultures have been reported. If pharmacy records are computerized, a list of medications dispensed could be printed to insure that all IV antimicrobial starts were recorded. If computerized lists of hospital admissions or diagnoses are available, these could be examined and compared to the Log and Incident Forms. Similar procedures could be used for handwritten records, if available.

Dialysis center personnel may be asked to allow CDC personnel or their representatives to examine dialysis center records for the purpose of validating one or more months of data. Such validation would be done only with the written permission of the medical or administrative director of the dialysis unit.

### **Data analysis**

If data are recorded on paper forms and forwarded to CDC, the data will be entered into a computer database at CDC. If the data is entered into a computer database at the center, data analysis can be done by personnel at the center using a program supplied by CDC.

The number of various types of bacterial infections, hospitalizations, and IV antimicrobial starts per month will be tabulated, and rates of these events per 100 patient-months will be calculated. An example of the calculation of patient-months is: if a center treated 50 patients during the first week in January and 52 during the first week in February, and 48 during the first week in March, this center would have 150 patient-months in the first three months of the year. If 2 bloodstream infections occurred during this time, the overall bloodstream rate would be  $(2/150) \times 100 = 1.33$  bloodstream infections per 100 patient-months.

Infections will be categorized as per the table below. Rates will be calculated separately for the four types of vascular access (fistulas, grafts, and temporary or permanent catheters). This table is for data analysis and interpretation, and personnel do NOT have to use it while collecting data. Clinical signs of infection of the access site include pus, redness, or increased swelling.

Category	IV antimicrobial therapy or hospitalization	Blood culture	Clinical signs of infection	Suspected source of positive blood culture
Vascular access-related BSI	Yes	Positive	Access or none	Access or uncertain
Vascular access infection without BSI	Yes	Not done or negative	Access	Not applicable
Other bacteremia	Yes	Positive	Nonaccess, or none	Nonaccess
Infections other than access	Yes	Not done or negative	Nonaccess	Not applicable

BSI denotes bloodstream infection

Nonaccess denotes a site other than the vascular access

### **Data release and publication**

Data that are forwarded to CDC will be aggregated and analyzed at CDC. Periodically, the data will be released to participating dialysis centers. If appropriate, publications will be prepared and authored by CDC.

### **Records Management and Protection of Confidentiality**

This protocol has been approved by the CDC Institutional Review Board (IRB) (Protocol 2213). Participating centers can rely on the CDC IRB, or they can submit the protocol to their own IRB, as appropriate. This surveillance project involves collection of data from existing clinical records and does not include any intervention(s). Therefore, a waiver of informed consent has been requested and received from the CDC IRB.



Participating dialysis centers should take appropriate steps to maintain the confidentiality of any information collected as part of this project. Any data that are transferred from participating centers to CDC will have all personal identifiers, including patient names and social security numbers, removed or encrypted. If center personnel collect data on paper forms, the forms should be photocopied, and then the top of the form containing personnel identifiers should be removed, prior to transmittal. If center personnel collect data in a computer database prior to transmittal to CDC, all personal identifiers (i.e., name and social security number) will be encrypted so that only the center entering the data will be able to decrypt it.

## **PERSONNEL AND RESPONSIBILITIES**

At each participating dialysis center, one person should be identified as the primary contact person who has responsibility for data collection and transmittal to CDC. At CDC, the following personnel will be responsible for coordination, answering questions, aggregating data, analyzing data, and preparing reports:

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Medical Epidemiologist, Hospital Infections Program

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## **TIMETABLE**

Completion of protocol: September 1998

Approval of the CDC IRB: November 1998

Submission for Office of Management and Budget (OMB) approval: December 1998

General availability of the system: March 1999

## **LIST OF ATTACHMENTS**

1. Agreement to participate
  - 1a. Letter to dialysis centers
2. Census
3. Log
4. Incident Form

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## Attachment 1. Agreement to participate.

Form Approved OMB No. 0920-0442 Exp. date:

2/1/2002

## Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers

Name of dialysis center: \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

Fax \_\_\_\_\_

Email address \_\_\_\_\_

HCFA provider number \_\_\_\_\_

As described in the introductory invitation letter, CDC will use the data for surveillance purposes only, and has obtained an assurance of confidentiality to protect the data. However, a condition of participation is your agreement to report outbreaks or other problems of public health importance identified in this surveillance system, and for which you have been contacted by CDC, to the local or state public health authorities.

We agree to participate in “Surveillance for Bloodstream Infection and Vascular Access Infections in Outpatient Hemodialysis Centers.” We understand that participation is voluntary and we can discontinue our participation at any time.

The primary contact person listed below agrees that data collected and transmitted to Centers for Disease Control and Prevention (CDC) will be complete and accurate, to the best of his or her knowledge.

Primary contact person:

Name (printed) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

Medical Director or Administrator

Name (printed) \_\_\_\_\_ Title \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Attachment 1. Agreement to Participate, page 2.

Name of dialysis center: \_\_\_\_\_

HCFA Provider number \_\_\_\_\_

*Answer the following questions based on your dialysis center's policy. If your center has no policy, answer based on the most commonly followed procedure.*

For puncture of a graft or fistula, answer:

- N Y This dialysis center has a written policy for puncture of graft/fistula
- N Y Area washed with antibacterial soap
- N Y Area washed with other, specify: \_\_\_\_\_
- N Y Puncture site wiped with povidone-iodine (betadine, iodophor)
- If yes,
- Number of pads/swabs used: \_\_\_\_\_
- Is the povidone-iodine left on \$3 minutes or allowed to dry? N Y
- N Y Puncture site wiped with other, specify: \_\_\_\_\_

For dressing change of central catheters, answer:

- Y N This dialysis center has a written policy for catheter dressing changes.
- Y N Staff person is required to wear a mask during dressing change.
- Y N Patient is required to wear a mask during dressing change.
- Y N Staff are required to wear clean nonsterile gloves to remove old dressing
- Y N Staff are required to wear sterile gloves to clean the area and apply new dressing.
- Y N If drainage is found at the exit site (i.e., the place where the catheter enters the skin),  
drainage is removed with (specify): \_\_\_\_\_
- Y N Exit site wiped with povidone-iodine (betadine, iodophor).
- Y N Antibacterial ointment applied to exit site during dressing change.
- Y N Dressing applied over exit site at least once weekly.

Specify type of dressing used over catheter:

\_none \_gauze \_band-aid \_transparent \_other (specify) \_\_\_\_\_

For access of central catheters, answer:

- Y N This dialysis center has a written policy for access of catheter.
- Y N Staff person is required to wear a mask during access.
- Y N Patient is required to wear a mask during access.
- Y N Staff are required to wear sterile gloves to clean the area and do access.
- Y N Catheter port site (usually a rubber diaphragm) wiped with povidone-iodine (betadine, iodophor).
- If yes,
- Number of pads/swabs used: \_\_\_\_\_
- Is the povidone-iodine left on \$ 3 minutes or allowed to dry? Y N
- Y N Catheter port site wiped with other (specify) \_\_\_\_\_

Specify type of dressing used over catheter:

\_none \_gauze \_band-aid \_transparent \_other (specify) \_\_\_\_\_

Regarding antimicrobial use, answer

- Y N This center has a written policy regarding antimicrobial use
- Y N This center has access to a computerized listing of antimicrobials received by patients

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

Attachment 1a. Letter to Dialysis Centers.

Dear Dialysis Center Personnel:

As you know, bacterial infections are major problems in hemodialysis patients. Therefore the Centers for Disease Control and Prevention (CDC) has established a voluntary surveillance system, "Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers." We would like to invite your dialysis center to participate in this project.

Each month, participating centers will report the number of chronic hemodialysis patients treated, and supply information on patients hospitalized or treated with an intravenous (IV) antimicrobial. Data will be forwarded to the CDC for analysis, and routine reports will be compiled and sent to participating centers. At their option, centers may enter and analyze their own data using programs supplied by CDC. We hope that these data will facilitate quality improvement measures.

This study is entirely voluntary. Dialysis center personnel decide whether to participate, and may elect to discontinue participation at any time. Patient names or personal identifiers will not be reported to CDC.

In order to assure the confidentiality of the sources and the data it collects for this surveillance of bloodstream and vascular access infections in outpatient hemodialysis centers, the CDC Hospital Infections Program has obtained authorization to collect this data under the protection of Section 308(d) of the Public Health Service Act. The 308(d) confidentiality assurance affords this data the greatest protection against disclosure that CDC, as a Federal research agency, can provide under Federal law. The legislation stipulates that no information in a project protected by 308(d) can be used for any purpose other than the purpose for which it was supplied, nor be published or released in an identifiable format unless the establishment or person supplying the information or described in it has consented to such release.

As stated above, CDC will use the data for surveillance purposes only. However, a condition of participation is your agreement to report outbreaks or other problems of public health importance identified in this surveillance system, and for which you have been contacted by CDC, to the local or state public health authorities.

Thank you for considering participation in this surveillance system.

Yours truly,

Jerome I. Tokars, MD, MPH

Elaine R. Miller, RN, MPH

## Attachment 2

2/1/2002

Form Approved OMB No. 0920-0442 Exp. date:

**CENSUS FORM**

Provider number    \_ \_ \_ \_ \_

Month, year        \_ \_ / \_ \_ \_ \_

Record the number of chronic hemodialysis patients who received hemodialysis at your center at least once during the first week of the month.

Count each patient only once. If a patient has both an implanted access (graft or fistula) and a catheter, count this patient as having the catheter.

Vascular access type	Number of chronic hemodialysis patients
Graft	
Fistula	
Temporary catheter (noncuffed)	
Permanent catheter (cuffed)	
Total patients (= the sum of patients with grafts, fistulas, temporary catheters, and permanent catheters)	

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.

Attachment 3. **LOG.**

Form Approved OMB No. 0920-0442 Exp. date:

2/1/2002

Complete one row for each hospitalization or in-unit IV antimicrobial start. Complete an Incident Form for each row on this Log.

REMOVE THIS COLUMN BEFORE MAILING TO CDC	Provider number _ _ _ _ _ Year _ _ _ _				
Patient's name	Date mm / dd	Circle H or A H=hospitalization A=IV antimicrobial start	Problem	LOG Number	Incident Form Complete d
	/	H A		1	Y
	/	H A		2	Y
	/	H A		3	Y
	/	H A		4	Y
	/	H A		5	Y
	/	H A		6	Y
	/	H A		7	Y
	/	H A		8	Y
	/	H A		9	Y
	/	H A		10	Y
	/	H A		11	Y
	/	H A		12	Y
	/	H A		13	Y
	/	H A		14	Y
	/	H A		15	Y
	/	H A		16	Y
	/	H A		17	Y
	/	H A		18	Y
	/	H A		19	Y
	/	H A		20	Y

**Assurance of Confidentiality:** The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).

Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC, Project Clearance Officer, 1600 Clifton Road, MS D-24, Atlanta, GA 30333, ATTN: PRA (0920-0442). Do not send the completed form to this address.



**INCIDENT FORM**—complete one form for each hospitalization or in-unit IV antimicrobial start.

1. Name: First <span style="margin-left: 100px;">MI</span> <span style="margin-left: 100px;">Last</span>		2. Social security number:	
<b>REMOVE TOP BEFORE MAILING</b>			
3. Provider number <span style="margin-left: 100px;">— — — — —</span>		4. Date <span style="margin-left: 100px;">— — / — — / — — — —</span>	
5. LOG Number <span style="margin-left: 100px;">— —</span>			
6. Incident type (circle H and/or A):			
H = Hospitalization		A = In-unit IV antimicrobial start	
6a. If this is a hospitalization, answer: After return to unit, was IV vancomycin given? <span style="margin-left: 20px;">N</span> <span style="margin-left: 20px;">Y</span>		6b. If this is an in-unit IV antimicrobial start, answer: Was IV vancomycin started? <span style="margin-left: 20px;">N</span> <span style="margin-left: 20px;">Y</span>	
7. Vascular accesses (circle all that the patient has): <span style="margin-left: 20px;">1 = graft</span> <span style="margin-left: 20px;">2 = fistula</span> <span style="margin-left: 20px;">3 = temporary catheter</span> <span style="margin-left: 20px;">4 = permanent catheter</span>			
8. Problem(s) that led to hospitalization or IV antimicrobial start (circle at least one, may circle more than one):			
a. Vascular access <b>infection</b> (pus, or redness, or increased swelling at vascular access site)			
b. Vascular access problem <b>WITHOUT</b> infection (clotting, bleeding, etc)			
c. Fever (\$100F oral or \$101F rectal)			
d. Wound ( <b>NOT</b> related to vascular access) with pus or increased redness			
e. Pneumonia (a new infiltrate or pneumonia seen on chest X-ray)			
f. UTI (urine culture with >100,000 organisms/ml with not more than 2 species isolated)			
g. Cardiovascular event (chest pain, heart attack, other heart problem, stroke, etc)			
h. Other, specify:			
9. Vascular access removed? <span style="margin-left: 20px;">N</span> <span style="margin-left: 20px;">Y</span>			
9a. If yes, circle the access that was removed: <span style="margin-left: 20px;">1 = graft</span> <span style="margin-left: 20px;">2 = fistula</span> <span style="margin-left: 20px;">3 = temporary catheter</span> <span style="margin-left: 20px;">4 = permanent catheter</span>			
10. Were <b>blood</b> cultures drawn in the unit before antimicrobial start, or within 1 day of hospital admission? <span style="margin-left: 20px;">N</span> <span style="margin-left: 20px;">Y</span> <span style="margin-left: 20px;">U</span>			
10a. If yes, result <span style="margin-left: 20px;">1 = positive</span> <span style="margin-left: 20px;">2 = negative</span> <span style="margin-left: 20px;">3 = unknown</span>			
10b. If <b>positive</b> , suspected source of positive blood culture:			
<span style="margin-left: 40px;">1 = vascular access</span> <span style="margin-left: 40px;">2 = a source other than the vascular access</span> <span style="margin-left: 40px;">3 = contamination</span> <span style="margin-left: 40px;">4 = uncertain</span>			
10c. If <b>blood</b> cultures were positive, complete the following:			
List organisms isolated from blood		Antimicrobial susceptibility	
List one code* or name per row		Methicillin, Oxacillin, or Nafcillin	Vancoymcin
—		S I R U	S I R U
—		S I R U	S I R U
11. Comments			
Fever: 100 F = 37.8 C <span style="margin-left: 20px;">101 F = 38.3 C</span> <span style="margin-left: 20px;">N=no</span> <span style="margin-left: 20px;">Y=yes</span> <span style="margin-left: 20px;">U=unknown</span> <span style="margin-left: 20px;">S=susceptible</span> <span style="margin-left: 20px;">I=intermediate</span> R=resistant			
*SA= <i>S. aureus</i> <span style="margin-left: 20px;">SE= <i>S. epidermidis</i></span> <span style="margin-left: 20px;">CNS=coagulase-negative staphylococci</span> <span style="margin-left: 20px;">PA=<i>P. aeruginosa</i></span>			